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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/647,522 | 08/25/2003 | Daniel C. Sigg | P-11031.00 | 2282 |

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| EXAMINER |
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KOHARSKI, CHRISTOPHER

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| ART UNIT | PAPER NUMBER |
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3763

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| MAIL DATE | DELIVERY MODE |
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12/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/647,522 | Applicant(s) SIGG ET AL. | |
| | Examiner CHRISTOPHER D. KOHARSKI | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10,12-17 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10,12-17 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/18/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply in which claims 1 and 43-45 were amended. Currently claims 1-6, 8, 10, 12-17 and 43-47 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, 12-13, 15, 17, 43-45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Abele et al. (USPN5,403,311). Abele et al. discloses an electro-coagulation and ablation and other electro therapeutic body tissue treatments.

Regarding claims 1-6, 8, 10, 12-13, 15, 17, 43-45 and 47, a catheter (Figures 3A-10) comprising: a catheter (60, Figures 9A-9B) body that defines an inner lumen; an extendable probe (66) within the inner lumen that delivers fluid (macromolecules) to a tissue site of a patient (col 10, ln 45-60) with an exit (tip of 66); at least one electrode (67) (or second shown in Figure 10) located on the catheter body and at a distal end to detect contact between the catheter and the tissue site (col 9, ln 1-45); and an electrical stimulus to the tissue site is delivered through the at least one electrode and the probe (col 9, ln 30-55) (cols 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 14 is rejected under 35 U.S.C 103(a) as being unpatentable over Abele et al. (USPN5,403,311) in view of Mulier et al. (5,807,395). Abele et al. meets the claim limitations as described above except for the electrode used for cardiac pacing.

However, Mulier et al. teaches a apparatus for RF ablation.

Regarding claim 14, Mulier et al. teaches a catheter (1) with a distal tip electrode (3) that is used for cardiac ablation and is disclosed as also being employed for measurement functions or pacing of heart tissue by application of low energy electrical stimuli (Figure 1) (col 6, ln 20-55).

At the time of the invention, it would have been obvious to use the teachings of Mulier to use the electrode of Abele et al. for cardiac pacing in order to better treat the patient in conjunction with the active drug treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mulier et al. (cols 3-4).

Claim Rejections - 35 USC § 103

Claim 16 is rejected under 35 U.S.C 103(a) as being unpatentable over Abele et al. (USPN5,403,311) in view of Epstein et al. (USPN6,835,193). Abele et al. meets the claim limitations as described above except for the delivery of specific macromolecules such as DNA, RNA, etc.

However, Epstein et al. teaches a device and method for controlled depth injections.

Regarding claim 16, Epstein et al. discloses a catheter comprising a catheter body (2) that defines an inner lumen (near 16); a probe (14) with a needle tip within the inner lumen that delivers fluid (from 400) to a tissue site of a patient; and at least one electrode (35) coupled to the catheter to detect contact between the catheter and the

tissue site. The catheter body (2) is capable of guiding the probe (14) to a tissue site with the probe being retractable and extendable (Figures 3-4) through a distal port (10) to deliver multiple therapeutic macromolecule compounds such as DNA (cols 2 and 17) (Figures 1-6).

At the time of the invention, it would have been obvious to add the therapeutic agents of Epstein et al. in order to aid in further tissue treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Epstein et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claim 46 is rejected under 35 U.S.C 103(a) as being unpatentable over Adele et al. (USPN5,403,311) in view of Moorehead (USPN5,147,332). Adele et al. meets the claim limitations as described above except for the pressure response exit port valves.

However, Moorehead teaches a multi-valve infusion catheter.

Regarding claim 46, Moorehead teaches a catheter device (Figure 2) used for infusion (Figure 1) comprising several distal end pressure responsive exit valves (16, 18).

At the time of the invention, it would have been obvious to add the distal end valves of Moorehead to the system of Adele et al. in order to control the infusion rate within the patient or prevent agent backflow. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled

Art Unit: 3763

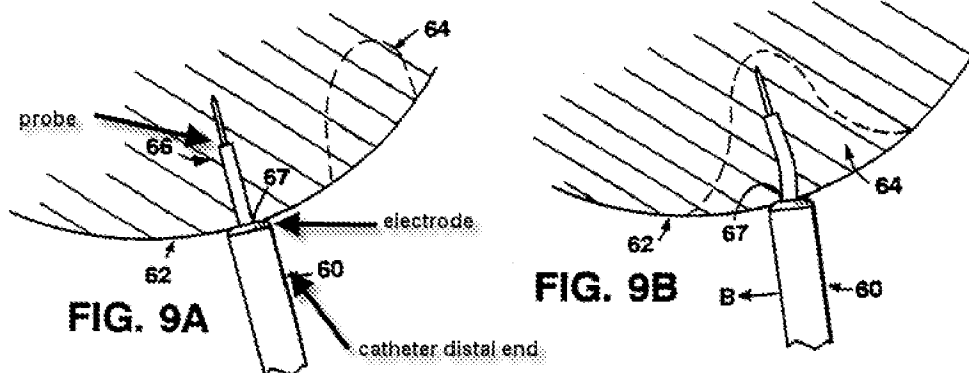
in the art would have combined the teachings in the references in light of the disclosure of Moorehead (cols 1-2).

Response to Arguments

Applicant's arguments filed 09/18/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Abele et al. reference does not disclose an electrode that is located on the catheter body at a distal end of the catheter body.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the electrode assembly of Abele et al. discloses a catheter body (60) that has a ring electrode (67) that is coupled to the distal end of the catheter body (see marked up Figure (9A below)).



The Examiner asserts the ring electrode that seals the distal end of the catheter meets the claimed limitations.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of distal end catheter assembly (see Figure 3) in which the electrode and sealing member is present with specific reference to the electrodes location and structure (i.e. singular point location).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/02/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763